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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/695,380	10/28/2003	Paul A. Spence	SPEN-03C	5321

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EXAMINER

MATTHEWS, WILLIAM H

ART UNIT	PAPER NUMBER
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3738

DATE MAILED: 05/04/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/695,380

Applicant(s)

SPENCE ET AL.

Examiner

William H. Matthews (Howie)

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 April 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 7,8 and 11-33 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 7,8 and 11-33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 11-1-05.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

1. Applicant's arguments filed 6-8-05 and 4-13-06 have been fully considered but they are not persuasive.
2. In the 6-9-05 arguments, Applicant states the limitations "preformed" and "entirely inside the heart" overcome the prior rejections involving Cox and Seguin et al. While the Examiner may have suggested the phrase "preformed" during the personal interview, the Examiner did not at that time believe "preformed" would overcome the art of record. As described in the Interview Summary mailed 5-3-05, agreement was not reached. Furthermore, Examiner believes the Cox and Seguin et al. references fully meet the limitation "preformed" because the devices are either formed with a segment extending out of the general plane (Cox) or are formed of material adapted to extend out of the general plane of the device (Seguin et al.). In addition, the newly added limitation "entirely inside the heart" is an intended use limitation which both Seguin et al. and Cox devices are capable of fulfilling. Therefore, the limitation "entirely inside the heart" does not further structurally limit the claims.
3. In the 4-13-06 arguments, Applicant describes the newly added independent claim 11 and bases patentability on the "preformed argument" described above. Examiner maintains the position set forth above that devices disclosed by Cox and Seguin et al. meet the structural limitations of the claims.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 7-8 and 11-33 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

6. Claims 7-8 and 11-33 are replete with the following terms and limitations not described in the specification or drawings:

claims 7 and 8: "posterior segment, anterior segment, preformed position".

claim 11: "anterior section, first and second anterior ends, posterior section".

claim 14: "posterior segment that extends away from the valve annulus plane".

(Note it is unclear where the posterior segment is defined or shown in any of figures 22-24 and where the basis for limitations in the claims dependent from claim 14.)

claim 15: entirely.

claim 17: entirely.

claim 18: lines 3-4.

claims 19-20: symmetric preformed posterior segment.

claim 21: lines 1-3.

claims 22-23: "selective narrowing".

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claim 24: "first and second segment ends" and "said arcuately shaped posterior segment extending away from the valve annulus plane".

claim 25: "a segment plane, said segment plane being bent".

claim 27: entirely.

claim 28: the specification only describes ring-shaped and J-shaped.

claim 30: the specification does not describe a selectively adjustable and lockable length to set the device in a preformed curvilinear shape to improve coaptation of the leaflet free margins in the systole configuration when in use. Rather, the description of figures 22-24 describe two methods of achieving the asymmetrical shapes: 1) permanently formed, or pre-formed and 2) adjustable and lockable ball and socket to reform the shape.

claim 31: entirely.

Claims depending from the above listed claims are rejected for further including said limitations.

Claim Rejections - 35 USC § 101

7. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 18 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The "posterior segment" is positively recited in conjunction with the human body (right commissure).

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 7-8 and 11-29 are rejected under 35 U.S.C. 102(b) as being anticipated by Seguin et al. US PN 5,607,471.

Seguin et al. discloses in figures 2 and lines 27-31 of col. 4 a device for supporting a heart valve comprising a ring asymmetric about a minor axis perpendicular to a major axis and having less area on one side of the minor axis. The ring is described as flexible and when implanted would inherently possess a segment extending downward relative to another segment when implanted because the natural heart valve annulus is not planar and contracts.

3. Claims 7-8 and 11-31 are rejected under 35 U.S.C. 102(e) as being anticipated by Cox US PN 6,250,308.

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Cox discloses in figures 2a and 2b a device for supporting a heart valve comprising an asymmetric ring having a section bent out of plane. An adjustable and lockable length feature is described at c5:59-c6:33.

Note as the claims currently require, the major axis may be drawn about any elongated portion of the annuloplasty device. Furthermore, the device is capable of being implanted entirely within the heart.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to William H. Matthews (Howie) whose telephone number is 571-272-4753. The examiner can normally be reached on Monday-Friday 10-6:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine M. McDermott can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read 'William H. Matthews', followed by a horizontal line.

William H. Matthews (Howie)
Examiner
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